UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SAMY ABDOU,

Plaintiff,

vs.

ALPHATEC SPINE, INC.,

Defendant.

CASE NO. 12-CV-1804 BEN (RBB)

ORDER DENYING ALPHATEC SPINE, INC.'S MOTION FOR SUMMARY JUDGMENT

[Docket No. 51]

Presently before the Court is Alphatec Spine, Inc.'s Motion for Summary Judgment. (Docket No. 51.) For the reasons stated below, the Motion is **DENIED.**

BACKGROUND

Plaintiff Samy Abdou, M.D., alleges that Defendant Alphatec Spine, Inc. willfully infringed U.S. Patent Nos. 7,951,153 ("the '153 patent") and 8,172,855 ("the '855 patent"), both of which are entitled, "Devices and Methods for Inter-Vertebral Orthopedic Device Placement." The patents at issue are directed toward the treatment of diseases of the spine.

The spine consists of a vertebral column and a spinal cord. The vertebral column provides support for the body and protects the spinal cord. Posterior to the vertebral column is the spinal cord, and anterior to the vertebral column is the aorta and vena cava, the body's two major blood vessels. The vertebral column is made up of individual vertebral bones, which are separated by an intervertebral disc space. The

disc space permits movement between vertebral bones and absorbs shock from the load transmitted through the vertebral column. Many medical problems involving the spine result from a problem of the disc (e.g., herniation) or compression of surrounding nerves. Treatment of these issues include implanting devices between vertebrae in order to adjust, align, and maintain the spatial relationship between them.

The '153 and '855 patents teach and claim devices and methods to target, access, and perform surgical work in the intervertebral space with minimal tissue dissection, including to place a sizable orthopedic device within. The '153 patent discloses devices by which a surgeon may access the intervertebral space by using a curved or arced portal ("insertion device") that allows for placement of a sizeable implant. The curved portal contains an internal bore or guide shaft, which extends from the proximal opening (nearest the surgeon) toward the distal end (at the disc space). An orthopedic implant is advanced through the bore and into the targeted disc space. The '855 patent discloses methods for targeting and accessing a targeted location within the spinal column, including between vertebrae, and for delivering an orthopedic implant into a target location, using devices similar to those described in the '153 patent.

A claim construction hearing was held on January 17, 2014. The Court declined to construe the ten sets of disputed claim terms found in the '153 and '855 patents, finding that they had a plain and ordinary meaning. (Docket No. 74.) Presently before the Court is Alphatec's Motion for Summary Judgement. (Docket No. 51.)

DISCUSSION

Alphatec argues that because the Court has previously construed the claims as permitting the mounting of the devices outside of the body, the asserted claims are invalid for failure to meet the written description and enablement requirements of 35 U.S.C. § 112(a).

Summary judgment is appropriate when "after opportunity for discovery and upon motion, there is no genuine dispute of material fact for trial and one party is entitled to judgment as a matter of law." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271

F.3d 1043, 1046 (Fed. Cir. 2001); FED. R. CIV. P. 56(c). All facts must be viewed in the light most favorable to the non-moving party, and all doubts must be resolved in the non-movant's favor. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1345-46 (Fed. Cir. 2000).

"Under 35 U.S.C. § 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1984). "Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001).

A. WRITTEN DESCRIPTION

"The specification shall contain a written description of the invention, and of the manner and process of making and using it." 35 U.S.C. § 112(a). "Specifically, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (internal quotation marks, citation, and alteration omitted). "Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000).

The Court finds that Alphatec has failed to prove a lack of written description by clear and convincing evidence. As discussed in the Claim Construction Order, the "mount," "anchor device," "fixation member," and "first member" limitations of the claimed devices are mountable, positionable, or attachable both inside and outside of the body. (Docket No. 74, at 4.) The claim language is agnostic as to whether the point of attachment is inside or outside of the body. (*See, e.g.*, '153 patent, at 7:35-37

("a first mount . . . mountable to a defined anatomical position relative to the target space"); *id.* at 8:31-33 ("a mount that is positionable at a defined anatomical relationship relative to the target space between the skeletal segments"); *id.* at 8:61-65 ("anchor device having . . . a second region [that] attaches onto a surface with defined spatial relationship to the disc space"); '855 patent, at 15:38-40 ("positioning an implant insertion assembly in proximity to the target location"); *id.* at 17:1-2 ("positioning . . . a first member of a targeting apparatus in proximity to the first vertebral bone").) In addition, the specifications indicate that no particular attachment location is required. (*See, e.g.*, '153 patent, at 5:45-49 ("The coupler 110 of the device 100 is then attached to an attachment point. It should be appreciated that the attachment point need not be the disc space itself. The coupler 110 can be attached directly to one of the vertebrae or to some other reference location."); '855 patent, at 13:66-14:1 ("In other embodiments, one or more anchors may be placed into the inter-spinous ligament, lateral to the inter-spinous space, into the pedicles or any other suitable anchor point.").)

This action is similar to *Gen-Probe Inc. v. Becton Dickinson & Co.*, 899 F. Supp. 2d 971 (S.D. Cal. 2012). One of the patents at issue in *Gen-Probe* claimed a seal or seals on a collection vessel that are penetrated by a fluid transfer device. *Id.* at 976. The defendant moved for summary judgment of invalidity of the asserted claims of the patent, on the basis that the patent specification failed to convey that the inventors invented a penetrable cap without a filter because the specification only described a patent with a filter. *Id.* at 978-79. This Court denied summary judgment because: (1) the embodiments with a filter were preferred embodiments, (2) an embodiment in the Summary of the Invention could "fairly be interpreted" as a cap lacking a filter, and (3) "the entire Summary of the Invention section [was] a series of paragraphs that describe various embodiments of the invention." *Id.* at 979-80. *Gen-Probe* is analogous to the present action in that the Court has found in the Claim Construction Order that the embodiments that describe the devices as attaching inside of the body are preferred

embodiments, and the patents claim devices that are mountable, positionable, or attachable both inside and outside of the body. As in *Gen-Probe*, "the Court cannot find that [Alphatec] has met it[s] burden to provide such clear and convincing evidence of invalidity that no reasonable jury could find otherwise." *Id.* at 980 (internal quotation marks omitted).

Alphatec's arguments to the contrary are not convincing. First, Alphatec argues that summary judgment should be granted because the patents at issue fail to provide any examples of the distal end of the mounting device attaching outside of the body. Alphatec is correct that "the lack of any disclosure of examples may be considered when determining whether the claimed invention is adequately described." *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1364 (Fed. Cir. 2011). However, "examples are not always required to satisfy the written description requirement." *Id.* Although relevant to the Court's analysis, this factor is not determinative.

Second, Alphatec cites *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111, 1119 (Fed. Cir. 2001), for the proposition that vague references in the patents referring to "other locations" cannot provide the requisite written description support. The patent at issue in *TurboCare* claimed a shaft seal used in fluid-driven devices such as steam turbines. *Id.* at 1113. On an appeal of the district court's granting of summary judgment for failure to meet the written description requirement, the plaintiff argued that "one of ordinary skill in the art would recognize that the only viable location for mounting a spring 'adjacent to said rings' would be between the casing shoulders and the shoulders of the outer ring portion of the segment, and therefore that the claimed subject matter was inherent in the original disclosure." *Id.* at 1119. However, the plaintiff conceded that the only support in the original disclosure for the location of a claimed spring was the language, "spring located . . . adjacent to said rings," from one of the original, rejected claims. *Id.* The court upheld the district court's granting of summary judgment, finding that

the "original disclosure [was] completely lacking in any description of an embodiment in which the spring is located between the casing shoulders and the inner surface of the outer ring portion of the ring segment." *Id.* *TurboCare*, however, is distinguishable from the present action. In *TurboCare*, the plaintiff attempted to limit the mounting location for the spring to between the casing shoulders and the shoulders of the outer ring portion of the segment, when such a limitation was not present in the general language of the original claims. Here, in contrast, Abdou argues that the claimed devices are *not* limited to being mountable, positionable, or attachable only inside of the body, which is consistent with this Court's finding that the patents at issue claim devices that are mountable, positionable, or attachable both inside and outside of the body.

Third, Alphatec cites *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 923 (Fed. Cir. 2004), for the proposition that generalized language is inadequate for satisfying the written description requirement. There, the court stated that "generalized language may not suffice if it does not convey the detailed identity of an invention." *Id.* at 923. By way of example, the court explained that "in the nineteenth century, use of the word 'automobile' would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels of axles, etc." *Id.* In addition, the court noted that "there [was] no language here, generalized or otherwise, that describe[d] compounds that achieve the claimed effect." *Id.* Here, in contrast, the parties do not dispute a term that describes a generic object, but rather the point of attachment for the devices at issue. In other words, the patents at issue here sufficiently convey the identity of the invention.

Alphatec has failed to meet its burden to provide such clear and convincing evidence of invalidity that no reasonable jury would find otherwise. *Eli Lilly*, 251 F.3d at 962; *see also Atlas Powder*, 750 F.2d at 1573 ("Under 35 U.S.C. § 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by

clear and convincing evidence."). Accordingly, Alphatec's motion for summary judgment based on lack of written description is **DENIED**.

B. ENABLEMENT

"A patent's specification must describe the invention and 'the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.'" *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (quoting 35 U.S.C. § 112(a)). "Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation." *Id.*

"The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation.'" *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003); *see also Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art."). Claims are enabled if "the trial and error required to practice the claimed invention [is not] unduly laborious or beyond the reach of one of ordinary skill in the art." *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004).

When determining whether undue experimentation would be required, courts may consider: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors "are illustrative, not mandatory." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991). The Court will consider each of the *Wands* factors in turn.

1. Quantity of Experimentation Necessary

Alphatec argues that attaching the distal end of the mounting device outside of the body would require a large amount of non-routine experimentation. According to Alphatec, if the distal end of the mounting device is not attached within the body, one of skill in the art would need to determine for each individual patient and surgery how to make the distal end of the curved member intersect the target space such that the target space can be accessed and the implant placed there without injuring the patient. (Foley Decl. ¶ 40.) Specifically, a physician would need to "(1) determine an appropriate mounting location in the operating room, (2) determine the precise spatial relationship between that location and the patient, (3) completely immobilize the patient in relation to the mounting location, so as to maintain the spacial relationship, (4) determine the appropriate geometry of the curved member based on the relationship, (5) plot a path that would be intersected by the curved member, (6) determine what critical anatomical structures were in the vicinity of the path and how to avoid them, and (7) reconfigure the components of the device based on the calculated spatial relationships and path." (Mot. at 18.) In addition, Alphatec argues, it would be difficult to maintain a fixed relationship between the mounting device and the target space because patients move during surgery. (Foley Decl. ¶ 44.) Patient movement may be caused, for example, by the patient's breathing, the impact of surgical tools on the patient, and the physician leaning against the patient. (*Id.*)

Abdou argues that any experimentation needed to make and use the claimed apparatuses and surgical techniques would be routine and trivial. First, Abdou submits evidence that proper patient positioning may greatly reduce involuntary patient movement. Patients may be secured to a surgical table using straps, surgical tape, bolsters, chest rolls, and other devices. (Moshirfar Decl. ¶ 23.)[1] Positioning patients

[1] Alphatec moves to strike the declaration of Ali Moshirfar, M.D., arguing that (1) it is conclusory, and (2) he did not have the requisite experience needed to be a person of ordinary skill in the art by the October 4, 2005 filing date of the '153 patent. (Docket No. 59-7.) First, Moshirfar's Declaration is sufficiently supported by other

in this manner allows a surgeon to position other equipment relative to surgical points of interest, and to maintain this positioning as needed throughout the surgical procedure. (*Id.*) Second, Abdou submits evidence that by using commonly known imaging techniques, a surgeon may locate a surgical point of interest within the patient's body. (*Id.* ¶ 43.) Furthermore, while the precise anatomy of each patient varies, the location of anatomical structures is known and predictable. (*Id.* ¶ 48.) Third, Abdou submits evidence that a surgeon may position and maintain other equipment relative to the surgical point of interest. As discussed below, it is well known in the art how to anchor surgical devices outside of the patient's body in ways that maintain the spatial relationship between the patient and the surgical device. (*Id.* ¶ 24.) Fourth, Abdou submits evidence that a surgeon may determine how to make the distal end of the insertion device intersect the target location by using the known distance from the targeted surgical location to the guide arm's center of rotation. (*Id.* ¶ 43.)

Abdou submits sufficient evidence to create a genuine issue of fact as to whether attaching the distal end of the mounting device outside of the body would require a large amount of non-routine experimentation. Accordingly, this factor weighs against finding a lack of enablement.

2. The Amount of Direction or Guidance Presented

Abdou submits evidence that the patents at issue provide sufficient direction and guidance to practice the claimed invention by attaching the device outside of the patient's body. In regards to positioning the mounting device, the patents teach that a surgeon may determine how to make the distal end of the insertion device intersect the target location by using the known distance from the targeted surgical location to

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evidence, including prior art. Second, Alphatec does not cite any authority for the proposition that in order to qualify as an expert witness, the expert witness must have had sufficient experience to qualify as a person of ordinary skill in the art at the time the patent was filed. Alphatec's motion to strike Moshirfar's Declaration is **DENIED**. In addition, Alphatec's evidentiary objections (Docket No. 59-7) are **OVERRULED** to the extent not inconsistent with this Order.

the guide arm's center of rotation. ('855 patent, at 2:54-57 ("Since the distance from the guide arm's center of rotation to the tip of the localizing needle is known, a guide arm of radius equal to that distance will necessarily form an arc that contains the needle point on its circumference.");[2] *see also id.* at 2:41-45, 7:30-38, 9:12-31, 9:42-44; '153 patent, at 4:20-22 ("The radius of curvature of the curved portion 140 can vary. In one embodiment, the radius of curvature is approximately equal to the length of the straight portion 130.").) In addition, the patents teach how to use imaging techniques to properly position the devices. *See* '153 patent, at 5:65-6:2 ("[O]ne or more x-ray image can be taken of the target location and the target location localized using the x-ray images by iteratively moving the mount so that the insertion device provides a guide toward the target location."); '855 patent, at 3:38-41 ("[T]here is disclosed a minimally-invasive surgical procedure, comprising localizing a surgical point of interest using an x-ray to identify the point of interest; relating the point of interest to a delivery apparatus . . . .").

Moreover, the law does not require the disclosure of "what is well known in the art." *Hybritech*, 802 F.2d at 1384. As explained below, methods for securely positioning a patient for spine surgery on surgical tables or frames, how to anchor surgical devices outside of the patient's body in ways that maintain the spatial relationship between the patient and the surgical device, and various imaging techniques were well known in the art at the time the patent was filed. Accordingly, a person of ordinary skill in the art ("POSITA") would need little direction or guidance to use the claimed inventions by anchoring them outside of the patient's body. (Moshirfar Decl. ¶ 44.)

In support of its argument that there is insufficient guidance presented in the patents regarding how the devices may attach outside of the body, Alphatec cites

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[2] Alphatec argues that where the localizing needle is taught in the patent, it is attached to screws and a platform that guide the needle into the target space. This Order cites to the descriptions of the localizing needle in the '855 patent only for the purpose of demonstrating that the patent teaches a method for determining the radius of a guide arm needed to form an arc with the target location on its circumference.

Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007), *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361 (Fed. Cir. 1997), and *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, 501 F.3d 1274 (Fed. Cir. 2007). These cases, however, are inapposite.

First, in *Liebel-Flarsheim*, the court found that the claims of the patents at issue, which covered injectors both with and without a pressure jacket, were not enabled. The court based its decision, in part, on the fact that the specification failed to describe an injector without a pressure jacket, and all figures and discussion referred to pressure jackets. *Liebel-Flarsheim*, 481 F.3d at 1379. The specification, however, explicitly taught away from an injector without a pressure jacket. *Id.* The court found that "where the specification teaches against a purported aspect of an invention, such a teaching is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention." *Id.* (internal quotation marks omitted). Here, in contrast, the Court has not found that the patents at issue teach against attaching the device outside of the body.

Second, Alphatec cites *Genentech* for the proposition that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech*, 108 F.3d at 1366. The patent at issue in *Genentech* claimed a method for producing hGH by cleaving an hGH-contained conjugate protein. *Id.* at 1363, 1366. The court determined "whether the specification would have enabled a person having ordinary skill in the art at the time of filing to use cleavable fusion expression to make hGH without undue experimentation." *Id.* at 1365. Although the specification did not describe how to make hGH using cleavable fusion expression, Genentech argued that "the knowledge of one skilled in the art was sufficient to provide all of the missing information and, more specifically, that the disclosure of a DNA encoding hGH, when combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable the practice of the claimed method." *Id.* The court found the patent to be invalid. *Id.* Specifically, the court found that the patent contained "no disclosure of

any specific starting material or of any of the conditions under which a process can be carried out." *Id.* at 1366. Rather, "[t]his specification provide[d] only a starting point, a direction for future research." *Id.* The court noted, in fact, that "no one had been able to produce *any* human protein via cleavable fusion expression as of the application date." *Id.* at 1367. The court concluded that "[w]here, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching." *Id.* at 1367-68.

Here, in contrast, the claimed invention does not involve unpredictable technology in the early stages of development. Rather, as discussed below, Abdou submits evidence that the prior art included methods for securely positioning a patient for spine surgery on surgical tables or frames, anchoring surgical devices outside of the patient's body in ways that maintain the spatial relationship between the patient and the surgical device, and using various imaging techniques. Unlike the patent in *Genentech*, the patents at issue here provide more than a starting point for future research.

Third, Alphatec cites *Automotive Technologies* in support of its argument that the patents at issue are not enabled because they contain lengthy explanations regarding how to practice the invention when the mounting device is attached inside the body, but not when it is attached outside of the body. The technology at issue in *Automotive Technologies* involved "crash sensing devices for deployment in an occupant protection apparatus, such as an airbag, during an impact or crash involving the side of a vehicle." 501 F.3d at 1277-78. Specifically, the invention was "directed to a velocity-type sensor placed in a position within a vehicle in order to sense a side impact." *Id.* at 1278. The court affirmed summary judgment of invalidity due to lack of enablement, basing its decision in part on the way the specification described mechanical side impact sensors in detail, but only briefly described electronic sensors. *Id.* at 1282. In addition, the court found that at the time the patent was filed, the plaintiff was not aware of any electronic sensors used to sense side impact crashes. *Id.*

at 1283. The court reasoned that "[g]iven that side impact sensing was a new field and that there were no electronic sensors in existence that would detect side impact crashes, it was especially important for the specification to discuss how an electronic sensor would operate to detect side impacts and to provide details of its construction." *Id.* at 1284. The court concluded that the "specification provide[d] 'only a starting point, a direction for further research' on using electronic sensors for sensing side impact crashes." *Id.* (citing *Genentech*, 108 F.3d at 1366).

Here, in contrast, the claimed invention is not part of a new field of technology. Rather, as discussed below, Abdou submits evidence that the prior art included methods for securely positioning a patient for spine surgery on surgical tables or frames, anchoring surgical devices outside of the patient's body in ways that maintain the spatial relationship between the patient and the surgical device, and using various imaging techniques. As stated above, the patents at issue here provide more than a starting point for future research.

Abdou submits sufficient evidence to create a genuine issue of fact as to whether the patents at issue provide sufficient direction and guidance to practice the claimed invention by attaching the device outside of the patient's body. Accordingly, this factor weighs against finding a lack of enablement.

3. The Presence of Absence of Working Examples

The absence of working examples weighs against enablement. *Auto. Techs. Int'l v. BMW of N. Am., Inc.*, 378 F. Supp. 2d 780, 817 (E.D. Mich. 2005), *aff'd* 501 F.3d 1274 (Fed. Cir. 2007). Here, the patents at issue contain no working examples in which the distal end of the mounting device attaches outside of the body. The absence of working examples supports finding a lack of enablement.

4. The Nature of the Invention

The '153 patent claims a relatively simple mechanical device, while the '855 patent claims a method for using that mechanical device. (Moshirfar Decl. ¶ 45.) Even Alphatec's expert witness, Kevin T. Foley, M.D., testifies that "the apparatus claims

recite a simple mechanical device." (Foley Decl. ¶ 52.) Although Alphatec argues that the claimed device is complex because it is used in minimally invasive spine surgery which involves significant health risks, this goes toward the seventh factor, the predictability or unpredictability of the art. Accordingly, this factor weighs against finding lack of enablement.

5. State of the Prior Art

The relevant time frame for determining the state of the prior art is measured from October 5, 2004, which is the earliest date to which the earliest filed patent at issue claims priority. *See* U.S. Patent Application No. 60/616,100 (provisional application for the '153 patent).

At that time, methods for securely positioning a patient for spine surgery on surgical tables or frames was well known in the art. A variety of positioning techniques existed, including placing the patient on his or her side, in the prone position, or on a surgical table or frame. (Moshirfar Decl. ¶ 23.) In addition, straps, wide tape, bolsters, chest rolls, sand bags, foot boards, buckled boots, and other supporting pads could be used to secure the patient to the surgical table or frame. (*Id.*) Numerous surgical reference guides describe such principles and techniques. (Pl.'s Resp. to Def.'s Statement of Uncontroverted Facts and Conclusions of Law., Exh. 4 [ARTHUR H. WHITE, M.D. ET AL., LUMBER SPINE SURGERY: TECHNIQUES & COMPLICATIONS, 86-102 (E. Klein ed., C.V. Mosby Co. 1987)], Exh. 5 [ROBERT G. WATKINS, M.D. ET AL., SURGICAL APPROACHES TO THE SPINE, 167-68 (Springer-Verlag 1983)].)

Moreover, how to anchor surgical devices outside of the patient's body, including to the surgical table, in ways that maintain the spatial relationship between the patient and the surgical device was also well known in the art. For instance, U.S. Patent No. 3,221,743, issued to Richard Thompson, M.D. in 1965 and entitled "System and Apparatus for Positioning and Securing Surgical Implements," claimed a surgical

retractor.[3] This patent claimed an "apparatus for positioning and supporting surgical accessories and implements in selected positions relative to an operating table and relative to the body of the patient supported upon the table." (*Id.*, Exh. 6 ['743 patent, at 2:11-15].) U.S. Patent No. 8,137,284, filed on October 8, 2003 and entitled "Surgical Access System and Related Methods," claimed various methods "of accessing a spinal target site." (*Id.*, Exh. 7 ['284 patent, claims 1, 17].) This patent's specification stated that "[a]ny number of suitable mounting units (not shown) may be employed to maintain the retraction assembly 10 in a fixed and rigid fashion relative to the patient. The mounting structure 20 may be coupled to any number of mechanisms for rigidly registering the mounting structure 20 in fixed relation to the operating site, such as through the use of an articulating arm mounted to the operating table." (*Id.* at 8:6-12.) In addition, such principles and techniques were well known and used in the art before 2004, as described in various surgical reference guides. (Moshirfar Decl. ¶ 24; Pl.'s Resp. to Def.'s Statement of Uncontroverted Facts and Conclusions of Law, Exh. 4 [LUMBER SPINE SURGERY: TECHNIQUES & COMPLICATIONS at 375].) References cited on the face of the asserted patents, such as U.S. Patent No. 5,976,146 (*id.*, Exh. 11, at Fig. 121), disclose mounting surgical devices outside of the patient's body in ways that maintain a spatial relationship to the surgical site.

Lastly, various imaging techniques, including x-ray, computed tomography, and fluoroscopy, have been practiced for decades. (Moshirfar Decl. ¶ 25.) These imaging techniques can be used during orthopedic surgery to identify, localize, and visualize bony and soft tissue structures. (*Id.*) Such principles and techniques were well known in the art long before 2004, and are described in various surgical reference guides. (*Id.*;

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[3] Alphatec argues that retractors do not qualify as prior art. According to Alphatec, retractors are inserted into the body after the surgeon has done significant surgical dissection to expose the anatomy, while the invention here consists of an insertion device that is pushed through tissue through a small incision. Although the function of the invention differs from the function of a retractor, this Order refers to retractors as prior art only for the purpose of establishing that a POSITA was familiar with how to anchor surgical devices outside of the patient's body.

Pl.'s Resp. to Def.'s Statement of Uncontroverted Facts and Conclusions of Law, Exh. 5 [SURGICAL APPROACHES TO THE SPINE, 101, 168].)

Accordingly, the state of the prior art weighs against finding a lack of enablement.

6. Relative Skill of Those in the Art

A POSITA includes surgeons with several years of experience in surgical procedures pertaining to the spine and with the corresponding instruments and tools, including minimally invasive procedures, instruments, and tools. (Moshirfar Decl. ¶¶ 22, 47; Buccigross Decl., Exh. 8, at 16.) A surgeon learns early in his or her training how to securely position a patient for spine surgery on various surgical tables or frames, anchor surgical devices outside of the patient's body, and use various imaging techniques such as x-ray, computed tomography, and fluoroscopy. (Moshirfar Decl. ¶¶ 23, 24, 25.) Accordingly, the Court finds that a POSITA at the respective application dates would have been trained and effective in proper patient positioning, locating surgical points of interest within the body using various imaging techniques, and positioning and maintaining surgical devices relative to the identified surgical points of interest. This factor weighs against finding a lack of enablement.

7. Predictability or Unpredictability of the Art

The "scope of enablement varies inversely with the degree of predictability involved." *Application of Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). Here, the pertinent art is minimally invasive surgical procedures pertaining to the spine. Minimally invasive spine surgery is difficult and risky. (Foley Decl. ¶ 52.) The surgeon must distally manipulate small tools. (*Id.*) Moreover, the art is not entirely predictable because the surgeon cannot directly visualize all of the body parts that he or she must avoid damaging. (*Id.*) Accordingly, this factor supports finding lack of enablement.

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8. The Breadth of the Claims

The scope of enablement varies inversely with the breadth of the claims. *Auto. Techs.*, 378 F. Supp. 2d at 818-19. The claims of the '153 and '855 patents are fairly broad. The '153 patent discloses a curved insertion device for delivering an orthopedic device to a target location using a mount that is positionable at locations inside or outside of the body that have a spatial relationship to the surgical target. (Moshirfar Decl. ¶ 49.) The '855 patent covers methods for delivering an orthopedic device onto a target location by identifying the target location with an imaging method, positioning a mount in proximity to the target location, and using a curved insertion in conjunction with the mount to access the target location. (*Id.*)

The patents encompass mounting points both inside and outside of the patient's body. (*Id.*) However, the mounting point is not unconstrained; it must have a spatial relationship to the target that allows for use of the device. (*Id.*) Accordingly, this factor weighs slightly towards finding a lack of enablement.

9. Conclusion

The absence of working examples, unpredictability of the art, and breadth of the claims weigh in favor of finding a lack of enablement. However, the quantity of experimentation needed, the amount of direction and guidance presented, nature of the invention, state of the prior art, and relative skill of those in the art weigh against finding a lack of enablement. Alphatec has failed to meet its burden to provide such clear and convincing evidence of invalidity that no reasonable jury would find otherwise. *Eli Lilly*, 251 F.3d at 962; *see also Atlas Powder*, 750 F.2d at 1573 ("Under 35 U.S.C. § 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence."). Accordingly, Alphatec's motion for summary judgment based on lack of enablement is **DENIED**.

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CONCLUSION

For the reasons stated above, the Motion for Summary Judgment is **DENIED**.

IT IS SO ORDERED.

DATED: June 12, 2014

HON. ROGER T. BENITEZ
United States District Judge